Title of Research Study: Effect of N-803 on B Cell Follicles in Antiretroviral Treated HIV Disease, protocol version 4.3 (11/29/2021)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institutes of Health (NIH). Study drug is manufactured and provided by NantKwest, Inc.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. There is no guarantee participants will directly benefit from this study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to be a possible participant in this research study because your healthcare provider has determined you are living with HIV, you have been taking HIV medications at least 2 years, and you are in overall good health.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study involves treatment with the immune stimulating drug N-803, which is a new agent that binds with interleukin 15 (called IL-15 for short). IL-15 is a naturally occurring substance produced by the body to stimulate cells of the immune system to increase in number and become more active.

The primary reason for this study is to determine the safety of N-803, and to determine the effect of N-803 on your immune system's ability to react to the HIV that is present in your lymph tissue, even when you are taking HIV medications and have very little or no measurable HIV in your blood.

In this study you will receive a total of three doses of the study drug, N-803. You will receive one dose every three weeks, over the course of nine weeks. N-803 will be administered via subcutaneous (under the skin) injection and you will be monitored for up to 2 hours after receiving each dose of study drug.

N-803 is not approved by the FDA, and the use of the study product is considered experimental.

How long will the research last?

We expect that you will be in this research study for up to six months.

What will I need to do to participate?

The study doctor will determine if you are eligible to join this study. If you are eligible and decide to join, you will be asked to agree to follow the instructions given by the research staff during the study. You will be asked to attend up to 20 study visits. At these visits you will undergo two lymph node biopsies, undergo two colonoscopies with biopsies, undergo two leukapheresis procedures, receive three doses of study drug, provide four stool samples, and your blood will be drawn up to 15 times. If you are unable to undergo the leukapheresis procedure based on your apheresis consultation appointment, a large volume blood draw (60mL – about 4 tablespoons) will be substituted.

During the COVID-19 pandemic, we will ask you about COVID-19 symptoms before each visit and collect a nasal swab for COVID-19 testing prior to your injection and biopsy visits. You will be required to isolate at home after your COVID-19 test prior to your injection and biopsy visits.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

You will likely experience a skin reaction at the site of the study drug injection and swollen lymph nodes. You may feel tired, achy, and mildly feverish, similar to how you might feel if you were getting sick. These symptoms could last for 7-10 days after each injection. In a few previous study participants, minor irregularities of the electrical activity of the heart (known at QTc prolongation) were noted using an EKG test. These irregularities resolved without intervention. At this point in time, there is no clear connection between administration of N803 and these irregularities. Although it is not expected, you may experience one of these minor irregularities of the electrical activity of the heart (QTc prolongation). N-803 has been used in a limited number of humans, so unexpected serious unwanted side effects could occur, such as an inability to control your HIV disease. This study also involves two surgical groin lymph node biopsies, two colonoscopies with gut biopsies, and two leukapheresis procedures, all of which procedures can cause discomfort and can very rarely cause serious effects.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, you will be provided with results of all clinical lab tests obtained during this study. If there are any abnormalities noted on pathology review of your biopsy samples you will be notified of these results as well.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 10 people in Minnesota will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

During the COVID-19 pandemic, you will be screened for COVID-19 symptoms before you arrive for any visits, and you will have a COVID-19 test done three days before any injections or procedures. The COVID-19 test is done via nasal swab at the research clinic, and is not billed to you.

Screening Visit:
During the screening visit, which may be split into two visits, you will be asked to come to the research clinic at the University of Minnesota. You and a member of the study team will review this consent form in detail and your questions about the study will be answered. After signing the consent form, your medical history will be taken. You will undergo a physical exam performed by a physician. Your vital signs will be checked. You will be asked to provide information about your current health conditions, medications you are currently taking and data such as your contact information, age, date of birth, and ethnic origin.

We will collect about 2 tablespoons of blood to conduct clinical lab and research lab testing. We will evaluate your blood for information about your organ function (heart, liver, kidney, and lung) and immune function. We will also test for tuberculosis, Hepatitis B and C, and measure your HIV viral load. You will also have an electrocardiogram (EKG), which is a painless electronic tracing of your heart rhythm. If your EKG results are not clear, you may have an echocardiogram and/or a treadmill exercise test which measures how well your heart functions and pumps blood. All women of childbearing potential will have a pregnancy test, as a negative test is required to participate in the study. You will be sent home with a stool collection kit and asked to collect stool within 3 days of your next study visit.

Entry Visits:
You will return the stool sample you have collected to the research team.

In the week before you undergo leukapheresis, you will be asked to come to the University of Minnesota Medical Center, Fairview Blood Donor Center for a short leukapheresis screening visit, which involves providing health information to Blood Donor Center staff and having your veins examined to see if you are a good candidate for the procedure. If you are not a good candidate for the procedure, you may have a large volume blood draw scheduled instead.

Seven to fourteen days before you are scheduled to have your first dose of study drug, you will be asked to return to the Blood Donor Center. White blood cells will be collected from your blood using a process called “leukapheresis.” To collect the cells a needle will be put into a vein in each arm. The blood will leave through one arm, pass through a machine that separates out the targeted cells, and the rest of the blood will be returned to you through your other arm. The process can take up to six hours, during which you will need to sit quietly.

One to seven days later, you will be asked to come to the research clinic. You will be asked to provide information about your current health conditions, medications you are currently taking, and changes to health that may have occurred since your last visit. A physical exam will performed. Your vital signs will be checked. You will have a pulmonary function test, which is a breathing test that measures how fast air moves in and out of the lungs. This will show us that your lungs work normally. Blood will be drawn for clinical and research lab testing (about 2 tablespoons). A colonoscopy with biopsies and a lymph node biopsy will be performed.

Colonoscopy: A colonoscopy with biopsy will be done by a doctor who specializes in this test. A colonoscopy is a visual exam of the lining of the large intestine using a flexible tube with a tiny camera on the end. This instrument allows the doctor to view the inside of your rectum and colon and take a small piece of tissue from the small bowel. The bowel must first be cleared of all residue before the test. To do this, you will be asked to stop eating solid foods at 4 pm the day before your procedure (it is okay

to drink clear liquids such as Gatorade, broth, etc.). At 6 pm you will start to drink 32 ounces of a solution that will make you have bowel movements until your bowel is emptied. You will drink another 32 ounces of the solution at 10pm. In the morning before coming to the research clinic, you will drink another 10-12 ounces of a different solution that will make you have bowel movements until your bowel is emptied. You can continue to drink clear liquids until 2 hours before your appointment.

The colonoscopy will be performed at the University of Minnesota Medical Center, Fairview on the same day as your lymph node biopsy. You will lie on your left side or on your back during the exam. The doctor will insert the colonoscope into your rectum. The tube is about the size of an adult's forefinger. The colonoscope will be gently guided through your colon. The doctor will put air into your colon to see it better. You may experience some cramping and feeling full. Some of the air will be removed at the end of the exam. You may pass any remaining air. 14-18 small tissue samples will be collected from your small bowel and large bowel during the procedure. These biopsies will not hurt.

The entire procedure usually takes less than an hour. There is little pain; however, mild sedation is given to relieve anxiety and discomfort. After the colonoscopy, there may be slight discomfort, which quickly improves with the expelling of gas. Most people can resume their regular diet later that day. Because of the sedative, you will not be able to drive home after the procedure. We will arrange for transportation for you if needed.

Lymph Node Biopsy: A lymph node and a small amount of surrounding fat in your groin will be removed by a surgeon. This will be minor surgical procedure performed at the research clinic. The lymph node will first be identified using an ultrasound, which is a small probe that will be placed on the surface of your skin. The actual surgery will only take 30-40 minutes but you will need to be at the research clinic for about 6 hours. You should not eat or drink anything for at least 6 hours before surgery. The groin area will be scrubbed with an antiseptic solution. Local anesthetics will be injected to numb the area. An incision between 1 and 3 inches will be made. The lymph node will be uncovered and removed. A lymph node is about the size of a peanut. The surgeon will close the wound with stitches, and then a bandage will be put over the wound. After a period of at least 4 hours you will be allowed to leave the biopsy appointment. You will be asked to remain inactive until the next morning. You and the surgeon will discuss the use of a drug to relieve any pain. The entire procedure from the time you enter the research unit until you are discharged should be no longer than 8 hours.

Three to 4 days after the procedure you may be examined in the clinic. The wound will be examined and you will be asked questions about pain, drainage from the wound, or discomfort. If there is any sign of infection you will be referred back to the surgeon for another examination and a prescription of antibiotics or another appropriate treatment. The exact antibiotic will be chosen by the surgeon or investigator.
The surgeon will advise you as to the best way to manage stitches that are in place. They may ask you to come back to clinic 5-7 days after the procedure to have the stitches removed, or the stitches may be the dissolving type. You will be fully informed of which type you have.

Dosing Period
You will be asked to come to the research unit for 6 visits over 7 weeks.

Dose 1 - Day 0:
You will be asked to come to the research unit. You will be asked about medications you are currently

taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. You will also have an electrocardiogram (EKG). You will be asked to provide a stool sample. Blood will be drawn for clinical and research lab testing (about 3 ¼ tablespoons). All women of childbearing potential will have a pregnancy test. Approximately 30 minutes before receiving study drug you will be given pre-medications to help with possible side effects of the study drug. You will receive the study drug by subcutaneous injection and be monitored for 2 hours at the research clinic.

Dose 1 - Day 7:

You will be asked to come to the research unit. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. Blood will be drawn for clinical and research lab testing (about 3 tablespoons). You will also have an electrocardiogram (EKG).

Dose 2 – Day 21:

You will be asked to come to the research unit. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. You will also have an electrocardiogram (EKG). You will be asked to provide a stool sample. Blood will be drawn for clinical and research lab testing (about 3 ¼ tablespoons). All women of childbearing potential will have a pregnancy test. Approximately 30 minutes before receiving study drug you will be given pre-medications to help with possible side effects of the study drug. You will receive the study drug by subcutaneous injection and be monitored up to 2 hours at the research clinic. You will be sent home with a stool collection kit and asked to collect stool within 3 days of your next study visit.

Dose 2 - Day 28:

You will be asked to come to the research unit. You will return the stool sample you have collected to the research team. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. Blood will be drawn for clinical and research lab testing (about 3 tablespoons). You will also have an electrocardiogram (EKG).

Dose 3 – Day 42:

You will be asked to come to the research unit. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. You will also have an electrocardiogram (EKG). You will be asked to provide a stool sample. Blood will be drawn for clinical and research lab testing (about 3 ¼ tablespoons). All women of childbearing potential will have a pregnancy test. Approximately 30 minutes before receiving study drug you will be given pre-medications to help with possible side effects of the study drug. You will receive the study drug by subcutaneous injection and be monitored up to 2 hours at the research clinic.

Dose 3 – Day 49:

You will be asked to come to the research unit. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. Blood will be drawn for clinical and research lab testing (about 3 tablespoons). You will also have an electrocardiogram (EKG). You will be sent home with a stool collection kit and asked to collect stool within 3 days of your next study visit.

Post dosing period (7-14 days after dose 3)

You will be asked to come to the Blood Donor Center. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. Leukapheresis will be performed. If you are not eligible for the leukapheresis procedure, a large volume (60mL, or about 4 tablespoons) blood draw will be substituted.

One to seven days later you will be asked to come to the research unit. You will return the stool sample you have collected to the research team. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. You will have a short physical assessment and your vital signs will be checked. You will have a pulmonary function test. Blood will be drawn for clinical and research lab testing (about 3 tablespoons). A colonoscopy with biopsies and a lymph node biopsy will be performed. Just like for your first colonoscopy, you will need to follow the same preparation regimen.

One to seven days after the procedures you will be asked to come to the research unit for a healing assessment. The wound will be examined and you will be asked questions about pain, drainage from the wound, or discomfort.

Follow-Up Visits

One, two, and three months after your last dose of study drug, you will be asked to come to the research unit. You will be asked about medications you are currently taking and changes to your health that may have occurred since your last visit. Your vital signs will be checked. Blood will be drawn for clinical and research lab testing (about 3 tablespoons).

After your two month visit, you will be sent home with a stool collection kit and asked to collect stool within 3 days of your next study visit. You will return this stool sample to the study team three months after your last dose of study drug.

Unscheduled Visits

During the study, you may be asked to return to the research unit for unscheduled visits for additional testing if you have abnormal lab values or to follow-up on a specific side effect or symptom.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending visits as requested, sharing information with us about changes in your health or medications while you are on study, and about any reaction(s) you experience during the study drug dosing period.

Vaccines & Medications Not Allowed During the Study

You will be asked not to receive vaccines (other than for influenza or SARS-Cov-2) or take any strong drugs that directly affect your immune system unless they are medically necessary. These might include prednisone and other powerful anti-inflammatory steroid drugs. You will also be encouraged not to change your antiretroviral drug regimen unless there are side effects or they stop working. The decision on the best antiretroviral drug regimen to use during the course of this study will be left up to you and your primary/infectious disease health care provider.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave this study, decide to stop receiving study drug, or are asked to leave by the study doctor, you will be encouraged to complete all remaining scheduled visits and procedures, including lab testing. These tests are to protect you from any unexpected side effects.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

This research has several risks and you may experience side effects. You may experience all, some, or none of these side effects and the side effects may vary in severity. The severity may be mild, moderate or severe, up to and including death.

N-803 Risks

You may experience one or more of the risks listed below with N-803. In addition to these, there may be other unknown risks, or risks that are not anticipated in association with the drug. Some risks described in this consent document, if severe, may cause death.

The most common side effects seen in studies with subcutaneous (under the skin) injections have been fever, fatigue, chills, and an injection site reaction with an associated skin rash, which at times has been widespread. These localized skin reactions are common (occurring in more than 50% of patients). You will receive medications to reduce the risk and/or severity of expected side effects.

Risks of N-803 when given as a subcutaneous injection		
Very common (more than 1 in 10 patients experience)	Common (between 1 in 30 and 1 in 10 patients experience)	Rare (fewer than 1 in 30 patients experience)
• injection site reactions as described above • fever	• fatigue • decreased white blood cell count	• feeling tired or short of breath due to low red blood count (anemia) • buildup of fluids in the abdominal

Risks of N-803 when given as a subcutaneous injection		
Very common (more than 1 in 10 patients experience)	Common (between 1 in 30 and 1 in 10 patients experience)	Rare (fewer than 1 in 30 patients experience)
• low level of albumin as detected by blood tests *(albumin is an important protein in your blood that can tell us about your kidney health)* • chills • lymphadenopathy (swelling in the lymph nodes)	• swelling in hands and/or feet (edema) • muscle pain • achiness • vomiting • headache • abdominal pain • back pain	space which may cause belly swelling (ascites) • anorexia (poor appetite) • hematuria (blood in urine) • Arthralgia (joint pain) • immunogenicity - anti-N-803 antibodies have been detected in subjects receiving N-803. The impact of anti-N-803 antibody formation on the effectiveness and safety of N-803 is unknown. • short-term, low absolute lymphocyte (type of white blood cell) count

Details of selected risks associated with N-803

Injection Site Reaction

An injection site reaction, including pain and redness at the injection site, is a common side effect of N-803 and can be expected. However, an injection site reaction is likely to resolve on its own without any long-term side effects. If you have a reaction, photographs may be taken to document the reaction and to help determine when it resolves. If you experience itching, your study doctor can give you a cortisone cream to help improve your symptoms.

Lymphadenopathy

Lymphadenopathy is swelling in the lymph nodes in your groin or other parts of your body, usually on the side of the injection. This is an expected side effect of N-803 which resolves on its own without any long-term side effects.

Fever and Chills

To prevent or reduce the severity of the anticipated fever and chills, all patients will receive medications (acetaminophen and diphenhydramine) to help with these side effects before and after receiving doses of N-803.

Infections

There is a serious risk of infection that includes sepsis (infection in the blood) and bacterial endocarditis (infection of the heart). Signs of infection will be monitored by the study physician and study staff. If you develop an infection you will be treated with antibiotics and the study drug will be held for up to 1 week.

Leukapheresis

The leukapheresis procedure has several risks, similar to the risks of giving blood. You may feel tired, faint, or dizzy. You may experience a headache, nausea, or vomiting. It is possible you could experience

low calcium or other changes in your blood. Where needles are placed in the arm, bleeding, bruising, pain, injury, clot, or infection may occur. Severe bleeding in the arm is rare. Your blood will be thinned with citrate (an anticoagulant) during the procedure. This may cause temporary numbness or tingling of the fingertips or around the mouth, cramping, chills, or anxiety. Other risks related to leukapheresis include allergic reaction, damage to red blood cells, loss of platelets, seizures, and air in the heart or lungs. Should the machine break, you could lose up to 1 cup of blood, but this occurs rarely. Normally, the blood taken with this procedure is about 1 cup. Although very rare, there is a risk of serious problems such as heart attack, stroke, and death.

Lymph Node Biopsy

The lymph node biopsy procedure may cause pain, even though you have been given an anesthetic. There may be bleeding associated with the procedure. There is the risk of infection, however it is less than 2 percent. There is the possibility you might develop a seroma, which is a collection of fluid under the skin and around the wound. There is the possibility that you may develop a scar at the site of your lymph node biopsy. You will most likely experience pain and bruising after the lymph node biopsy. Occasionally, when we do a lymph node biopsy we cannot find the lymph node that was seen on ultrasound and/or felt prior to the procedure.

If any abnormalities that may impact your health are found on physical exam, or on analysis of lymph node tissue or blood samples, the research team will discuss this with you, provide you with a copy of the results, and, if you have signed a release of information, will discuss results with your primary doctor.

Colonoscopy with biopsy

The most common risks associated with colonoscopy are: abdominal cramping, minor bleeding from biopsy sites, if a polyp is removed, or if a blood vessel is nicked, anxiety, and a feeling of dizziness from the medications used to help you relax. A very rare complication of colonoscopy is perforation (hole or tear) of the intestine, which would likely require either surgical repair or use of hemostatic clips (clips that stop bleeding) and antibiotics.

Because you will be given sedating medications for the procedure, you will not be allowed to drive home at the end of the study day. We will arrange for transportation for you if needed.

If any abnormalities that may impact your health are found on physical exam, during the colonoscopy procedure or on analysis of tissue or blood samples, the research team will discuss this with you, provide you with a copy of the results, and, if you have signed a release of information, will discuss results with your primary doctor.

Electrocardiogram (EKG) Risks

An EKG is a test that measures the electrical signals that control heart rhythm. Small pads are attached to the skin on the chest, arms and legs. In rare instances skin may be irritated at the sites of pad attachments.

Echocardiogram Risks

An echocardiogram produces a graphic outline of the heart to evaluate the pumping action of the heart. Electrode pads are placed on your chest. You should not feel any pain during this test. You may experience discomfort from lying quietly for a long period of time.

Pulmonary Function Testing Risks
You may experience a feeling of lightheadedness from breathing through the spirometry tubing, which is tubing that connects to an instrument that measures the amount of air taken into and exhaled from the lungs. Also, there is a rare but serious risk of a collapsed lung (less than 1%).

Discomfort and Embarrassment Risks
Questions about recent sexual activity may cause embarrassment. Anticipation of a medical procedure may cause stress or anxiety. Physical examination of the groin may be uncomfortable and cause embarrassment. Discussion of past medical history or risk factors for HIV infection may be stressful and cause anxiety. You may decline to answer any questions that you do not feel comfortable answering.

Blood Sample Collection Risks (both regular and large volume collections)
The most common risks of blood sample collection are pain and infection at the puncture site, bruising, bleeding, a feeling of lightheadedness, and possible fainting.

Stool Collection Risks
You may find it distasteful to collect and store stool until your study visit.

Risks Associated with Future Study Participation
You may be excluded from future trials as a result of your participation in this study.

Other Risks
There is always the risk of a rare or previously unknown side effect occurring. These might be minor or be severe as to cause death.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You should not be or become pregnant, breastfeed, father a baby, and/or donate eggs/sperm on this research study or for four months after receiving the final dose of study drug. If you are sexually active, you must be willing to practice birth control.

a) Acceptable birth control is defined as the following:
    i) For female participants of childbearing potential, two of the following forms of contraception are required, one of which must be a barrier method:
        (1) Condoms (male of female) with or without a spermicidal agent
        (2) Diaphragm or cervical cap with spermicide
        (3) Intrauterine device (IUD) with published data showing that expected failure rate is < 1% per year
        (4) Tubal ligation
        (5) Hormone-based contraceptive such as oral birth control pills
    ii) Male participants participating in sexual activity that could lead to pregnancy must agree to at least one reliable method of contraception of the above listed

According to the World Health Organization and the United States Center for Disease Control and

Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while participating in this research study or for four months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You will stop receiving study drug and undergoing biopsies for this study; however, you will continue to be followed for safety assessments and outcome. Any pregnancy that occurs on study will be reported to the antiretroviral pregnancy registry.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for four months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. All research study procedures that are required to take part in the study will be covered by the study. If a test result indicates you may need follow-up care with your primary physician, that care will be billed as usual, to you or your insurance.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), NantKwest and its designees, the University of Minnesota Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance, the University of California, San Francisco, and other local, US, and international regulatory entities.

Any samples donated by you will be kept indefinitely for possible use in future HIV studies. This is a requirement for study participation. The sample will be labeled with a tracking number that will allow the investigators to know who donated the specimen and when it was donated. However, the specimen will not have any other information on it that might identify you.

Your information and samples may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you,

or to give any compensation to you or your family.

The research will not include whole genome sequencing.

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious, or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

I ❑ **agree** ❑ **do not agree** to have ❑ **my primary/infectious disease provider** and/or ❑ **myself** informed of any results from the clinical laboratory studies that might be important to my health.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you withdraw consent, do not follow directions, if the study shows signs of causing major medical harm to you, there is an unapproved change to the protocol that requires discontinuation of the study treatment, the study team cannot reach you, if you have a positive pregnancy test, or if you miss a dose of study drug. Also, the study sponsor may decide to end the study at any time. If you are asked to leave the study, the reasons will be discussed with you.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, you will be reimbursed for your time, effort, participation expenses like transportation and meals, and for completing the study visits and procedures listed here. You will receive: $50 for each screening visit; $50 for the leukapheresis screening visit; $300 for each leukapheresis procedure or large blood draw procedure (2 visits); $300 for each colonoscopy with biopsies (2 visits); $300 for each lymph node biopsy (2 visits); $50 for each visit that involves receiving a dose of study drug (3 visits); and $20 per short stay study visit (up to 10 visits). The maximum you may receive is $2300 for the completion of all study visits.

If you are traveling from far away, there may be additional reimbursement available to help with your travel costs. The study team can tell you if this applies to you.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. However, the name of the study is entered into the Greenphire account and will be associated with your name.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

For the Consent of Non-English Speaking Participants when an Interpreter is Used:
A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual